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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,885	03/14/2007	Martin Pera	2354/380	3366

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,885	PERA ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-113,115-121,170-175 and 177-181* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-113, 115-121, 170-175, 177-181* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 10/06/09 is acknowledged.

Claims 109-113, 115-121, 170-175, 177-181 are pending.

Claims 109-113, 115-121, 170-175, 177-181 drawn to an isolated detector of a cell type which identifies on the cell type a cell marker, characterized by binding to a GCTM-5 antibody are under consideration in the instant application.

2. Applicant's submissition of Declaration by Dr. Para, stating that the hybridoma having ECACC accession number 03101603 has been deposited under the Budapest Treaty and that said hybridoma will be irrevocably and without restriction or condition released to the public upon the issuance of a patent has obviated the previous rejection of claims under 35 U.S.C. 112 first paragraph regarding the deposit issue.

In view of the amendment, filed 6/12/02(Paper No. 13), the following rejections remain

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

4. Claims 109-113, 115-121, are rejected under 35 U.S.C. 102(a) as being anticipated by Schopperle et al (BBRC, 2003, pages 285-290) for the same reasons set forth in the previous Office Action, mailed on 05/06/09.

Applicant's arguments, filed 10/06/09 have been fully considered, but have not been found convincing.

Applicant assert that Schopperle et al., disclosed monoclonal antibody, which is directed to a single epitope. There is no suggestion that the antibody disclosed by Schopperle et al., binds the same epitope as antibody produced by hybridoma having ECACC accession number 03101603.

As initial matter it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01©

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

As has been stated previously, Schopperle et al., teach an monoclonal antibodies that can binds to surface membrane protein expressed on human embrional carcinoma, a malignant stem cell of testicular tumors (see entire document, Abstract and Materials and Method in particular). Said marker is biochemically and structurally similar to another testis tumor antigen GTTM-2. It is noted that the reference is silent about the recited antibody binding to a stem cell marker characterized by binding to a GCTM-5 antibody. However, it is noted both antibodies recognized antigens derived from membrane preparation from a testicular carcinomas and thus similarity between both markers would allow for cross-reactivity of the antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind the same stem cell marker as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

5. Claims 109-113, 115-121, are rejected under 35 U.S.C. 102(b) as being anticipated by Pera et al (Differentiation, 1998, IDS) for the same reasons set forth in the previous Office Action, mailed on 05/06/09.

Applicant's arguments, filed 10/06/09 have been fully considered, but have not been found convincing.

Applicant assert that Pera et al., disclosed monoclonal antibody, which is directed to a single epitope. There is no suggestion that the antibody disclosed by Pera et al., binds the same epitope as antibody produced by hybridoma having ECACC accession number 03101603.

As initial matter it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01©

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

As has been stated previously, Pera et al., teach a monoclonal antibodies, such as GCTM-1, GCTM-2 and GCTM-4 and GCTM-3 that can binds to surface membrane proteins expressed on human embrional carcinoma, a malignant stem cell of testicular tumors (see entire document, Abstract and Materials and Method in particular). Said marker are reported to be able to recognized a proteins with an apparent molecular weight of from 57 to 85kDA . It is noted that the reference is silent about the recited antibody binding to a stem cell marker characterized by binding to a GCTM-5 antibody. However, is it is noted that all antibodies recognized antigens derived from membrane preparation from a testicular carcinomas with similar apparent molecular weight and thus similarity between both markers would allow for cross-reactivity of the antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind the same stem cell marker as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

6. Claims 109-113, 115-121, are rejected under 35 U.S.C. 102(e) as being anticipated by WO ' 03/040355 or WO 01/98463 for the same reasons set forth in the previous Office Action, mailed on 05/06/09.

Applicant's arguments, filed 10/06/09 have been fully considered, but have not been found convincing.

Applicant assert that WO' 355 and WO' 463 only ., disclosed monoclonal antibody, which is directed to a single epitope. There is no suggestion that the antibody disclosed by WO' 355 or WO' 463 binds the same epitope as antibody produced by hybridoma having ECACC accession number 03101603.

As initial matter it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01©

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

As has been stated previously, WO'355., teaches a monoclonal antibodies, that can binds to surface membrane proteins expressed on human embryonic stem cell. Said markers are reported to have an apparent molecular weight of from 68 to 85kDA (see entire document, pages 17, 18 in particular). It is noted that the reference is silent about the recited antibody binding to a stem cell marker characterized by binding to a GCTM-5 antibody. However, it is noted that all antibodies recognized surface membrane proteins expressed on human embryonic stem cell with similar apparent molecular weight and thus similarity between both markers would allow for cross-reactivity of the antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind the same stem cell marker as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

WO'463., teaches a monoclonal antibodies, that can binds to surface membrane proteins expressed on human embryonic stem cell. Said markers are reported to have an apparent molecular weight of from 68 to 85kDA (see entire document, pages 17, 18 in particular). It is noted that the reference is silent about the recited antibody binding to a stem cell marker characterized by binding to a GCTM-5 antibody. However, it is noted that all antibodies recognized surface membrane proteins expressed on human embryonic stem cell with similar apparent molecular weight and thus similarity between both markers would allow for cross-reactivity of the antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind the same stem cell marker as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 170-175 and 177-181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schopperle et al., or Pera et al., or WO ' 03/040355 or WO 01/98463 each in view of U.S. Patent No. 4,281,061 for the same reasons set forth in the previous Office Action, mailed on 05/06/09.

Applicant's arguments, filed 10/06/09 have been fully considered, but have not been found convincing.

Applicant asserts that since Schopperle et al., or Pera et al., WO ' 03/040355 or WO 01/98463 are not prior art references, they can not be used in 103 type rejection.

Contrary to Applicant's assertion, it is the Examiner position that Schopperle et al., or Pera et al., WO ' 03/040355 or WO 01/98463 are prior art references and thus can be used for 103 type rejection.

Schopperle et al., or Pera et al., WO ' 03/040355 or WO 01/98463 does not teach a kit comprising a detector of a cell type which identifies on the cell type a cell marker, characterized by binding to a GCTM-5 antibody.

US Paten '061 teaches that reagents of the pharmaceutical compositions can be provided as kits as a matter of convenience , optimization and economy of the users (see col 22, line 62 - col 23, line 4 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Paten '061 to those of Schopperle et al., or Pera et al., WO ' 03/040355 or WO 01/98463 to obtain a claimed kit comprising a detector of a cell type which identifies on the cell type a cell marker, characterized by binding to a GCTM-5 antibody.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because assemble the reagents in a kit format a matter of convenience , optimization and

economy of the users as taught by US Paten '061 and the detector taught by Schopperle et al., or Pera et al., WO ' 03/040355 or WO 01/98463 can be in a pack or a kit for convenience and economy.

It is noted the only active ingredient in the claimed kit is a detector of a cell type which identifies on the cell type a cell marker, characterized by binding to a GCTM-5 antibody.

Although the kits comprise instructions, there is no patentable weight given to the instructions themselves. It would have been prima facie obvious to the ordinary artisan to include a piece of paper in the kit identifying the components therein at the time the invention was made.

It is noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Also, see In re Haller 73 USPQ 403 (CCPA 1947), where application of printed matter to old article cannot render article patentable and In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey , 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963).

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/ 272-0735

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644